

REMARKS

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 1-34 are currently pending and claims 15-18, 20, and 23-25 are under consideration. Claims 15-17, 20, and 24 have been amended. No new matter has been inserted. Support for the amendment of claims 15 and 17 can be found in the specification at least at page 3, line 37, and page 4, lines 11-17. Claims 16, 20, and 24 were simply amended for clarity.

The Examiner indicated that trademarks in the application should be capitalized wherever they appear. The specification has been amended accordingly.

The specification was objected to as containing an embedded hyperlink and/or other form of browser-executable code. The specification has been amended in order to obviate this rejection.

35 U.S.C. § 112

Claims 15-18, 20 and 23-25 were rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse this rejection.

The Examiner concedes that the specification is enabling for administering anti-TCCR antibodies in order to prevent, inhibit, or attenuate the differentiation of T-cells into Th2 cells. In the interest of advancing prosecution, Applicants have amended claims 15 and 17 to recite anti-TCCR agonist antibodies in order to obviate this rejection. As claims 16 and 23-25 are dependent on claim 15, they are also fully enabled. As claims 18 and 20 are dependent on claim 17, they are also fully enabled. Applicants respectfully request that this rejection be withdrawn.

Claims 17, 18, and 20 were further rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse this rejection.

The Examiner cites Lewis for the proposition that it is unclear whether enhancing Th1 responses is a desirable goal of immunotherapy, particularly in the case of asthma.

In response, Applicants direct the Examiner's attention to Huang et al., 2001, *J. of Immun.*, 166: 207-217. Huang demonstrated that Th1 cells can counteract Th2-mediated asthma in a rat model. Further, Huang's model is particularly relevant to treatment of clinical asthma because down-regulation occurred at the efferent or elicitation phase of the responses when Th2 cells are fully developed and capable of promoting asthma. Therefore, Huang supports the enablement of independent claim 17.

The Examiner further cites Lewis for the proposition that it may be difficult to predict the *in vivo* consequences of agents on T cell immunity from *in vitro* studies.

In response, Applicants point out that Lewis draws a distinction between approaches using antigen-specific immunotherapy (such as altered peptide allergens) and approaches that are not antigen-specific (such as anti-IgE antibodies). Lewis was referring to antigen-specific immunotherapy when discussing the difficulty of predicting *in vivo* consequences:

"Recent human trials of altered peptide ligands for the treatment of autoimmune disease indicate that it may be difficult to predict the *in vivo* consequences of these agents on T cell immunity from *in vitro* studies, and that peptide vaccination can induce early phase immune reactions."

Highlighting the distinction between the two approaches, Lewis states that "difficulties with the application of antigen-specific immunotherapy contrast with the recent success of humanized monoclonal anti-IgE therapy, suggesting that various approaches for atopic therapy that are not antigen-specific continue to have great potential" (see p. 648, emphasis added). In the dichotomy of Lewis, anti-TCCR antibodies, as featured in claim 17, are more akin to anti-IgE antibody therapy than to altered peptide ligands. Therefore, Lewis actually supports the enablement of claim 17.

For at least these reasons, Applicants assert that the specification enables one of skill in the art to practice the full scope of claim 17. As claims 18 and 20 are dependent on claim 17, they are also fully enabled. Applicants respectfully request that this rejection be withdrawn.

35 U.S.C. § 102(e)

Claims 15-18, 20, and 23-25 were rejected under 35 U.S.C. § 102(e) as anticipated by US 6,323,027 (Burkly et al.). Applicants respectfully traverse this rejection.

Burkly discloses monoclonal antibodies that bind to the gc chain of the IL-2 receptor. However, Burkly does not disclose or suggest administration of a “anti-TCCR agonist antibody” as featured by claims 15 and 17. As claims 16 and 23-25 are dependent on claim 15, they are also not anticipated or suggested by Burkly. As claims 18 and 20 are dependent on claim 17, they are also not anticipated or suggested by Burkly.

Claims 15-17, 23 and 25 were rejected under 35 U.S.C. 102(a) as inherently anticipated by Mattson et al. (WO 99/40195). Applicants respectfully traverse this rejection.

The Examiner alleges that Mattson discloses antibodies that recognize DCRS-1 and because of similarity between TCCR and DCRS-1 alleges that such antibodies would inherently prevent, inhibit, or attenuate the differentiation of T-cells into Th2 cells.

Applicants point out that inherency cannot be established by “probabilities or possibilities”. Rather, inherency requires that the matter is “necessarily present” in the cited reference. See MPEP § 2112; *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999). In this case, the Examiner concedes that the sequence of the polypeptide disclosed in Mattson (DCRS-1) is not identical to that of TCCR. For at least this reason, anti-TCCR agonist antibodies are not necessarily present in the disclosure of Mattson. Therefore, Mattson does not inherently disclose the administration of a “anti-TCCR agonist antibody” as featured by claims 15 and 17. Consequently, Mattson does not inherently anticipate the inventions of claims 15 or 17. As claims 16, 23, and 25 are dependent on claim 15, they are also not anticipated or suggested by Mattson.

Double Patenting

Claims 15-18, 20 and 23-25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-12 of

copending Application No. 10/663,158. In response, Applicants request that this provisional rejection be held in abeyance until allowable subject matter is indicated.

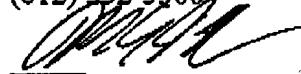
Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: 8/22/05


Mark E. Deffner
Reg. No. 55,103

